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(54) **Intraluminal stent**

**Intraluminärer Stent**

**Dilatateur intraluminal**

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(56) References cited:  
**EP-A- 0 357 003** **EP-A- 0 423 916**  
**EP-A- 0 480 667** **EP-A- 0 556 850**  
**WO-A-92/00043** **WO-A-92/06734**  
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**EP 0 645 125 B1**

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1

EP 0 645 125 B1

2

## Description

The present invention relates to a stent and, more particularly, to a self-expandable stent for expanding the lumens of a blood vessel or liver in cases where these are constricted.

In many situations, a device is required for expanding a constricted passageway of a blood vessel or the liver, or maintaining an open passageway through a vessel portion. Such situations arise, for example, when the blood does not flow smoothly or the passageways of the vessel portion are constricted due to arteriosclerosis or the growth of a tumor.

It is necessary to expand the passageway for smooth blood flow in such cases, and, for this purpose, devices are proposed and used for pushing a self-expandable elastic body into the constricted passageway. The elastic body is called a stent, which is, for example, a wire formed in a closed zigzag configuration, joined by a plurality of bends and wound cylindrically, as disclosed in EP 0177330.

Each section of the stent of the above structure is formed by a plurality of connecting members which link sections to each other for practical use. Thus, when the stent is placed in a bent portion of the lumen, a space is formed between a bend of a first stent section and a corresponding bend of a second stent section. This space allows restenosis of passageways or ducts in the body.

To avoid the use of numerous connecting members, U.S. Patent No. 4,733,665 discloses a graft which is formed by a tubular shaped member having first and second ends and a wall disposed between the first and second ends. The wall surface is formed by a plurality of intersecting elongate members, at least some of which intersect with one another intermediate the first and second ends of the tubular shaped member. In a graft of this configuration, since a plurality of elongate members intersect only with one another, the elasticity of the graft is formed only in the first and second ends of the tubular shaped member and it is weak therebetween.

EP-A-556850 (see preamble of Claim 1) discloses a stent comprising a helix of zigzag wire. Adjacent apices of the wire are joined together by separate joining members in the form of loops. One loop is provided for each joint, so the apices of the wire are not directly looped together.

It is an object of the present invention to provide a stent which can form a passageway for blood in its bent state yet prevent tissue from penetrating it.

Another object of the present invention is to provide a stent which maintains its length in case of constriction or expansion thereof.

A further object of the present invention is to provide a stent having a uniform elasticity.

According to the present invention, there is provided a self-expandable, cylindrical stent comprising: a single length of wire bent into a zigzag configuration by forming alternating peaks and valleys, the zigzag con-

figuration being spirally wrapped about an axis into a plurality of turns, said axis forming a longitudinal axis of the stent, and characterised in that peaks of one turn of the stent are interlocked with valleys of an adjacent turn of the stent by directly cross-linking said peaks and valleys.

Preferably, the wire has first and second end portions, each of which is bent towards and extends towards a central turn of the stent and is woven in and out of turns of the stent.

The distal ends of the first and second end portions may be hooked around a straight portion of a turn.

The length of wire may consist of a series of first and second straight sections joined by a plurality of bends consisting of lower and upper bends, wherein each of the first and second straight sections is defined between each of the upper and lower bends, the first straight section being longer than the second straight section and the upper bends of one turn being directly cross-linked with corresponding lower bends of an adjacent turn, and wherein the stent is resiliently compressible into a smaller diameter first shape in which all of the straight sections are arranged side by side and closely adjacent one another for insertion into a passageway with the bends having a stress therein, the stent being resiliently radially expandable by release of said stress into a second shape in which all of the straight sections define a generally circular or cylindrical configuration for pressing against a wall of the passageway.

Thus, the present invention provides a stent formed of one wire member which has a zigzag configuration which is then spiralled into turns, bends of the zigzag being cross-linked with each other at adjacent turns, and ends of the wire preferably being bent and woven between turns. The tips of the wire may be hooked around an intermediate turn.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figures 1A to 1E show several stages in the manufacture of a stent for expanding lumens;

Figure 2 shows a further stage in the manufacture of the stent;

Figure 3 is a perspective view of the stent;

Figures 4A to 4D show steps for implantation of the stent into a lumen of a blood vessel or liver; and

Figure 5 is a perspective view of another embodiment in which the stent is wrapped in a mesh and coated with silicon rubber.

Referring to Figure 1A, a wire 8 having upper and lower ends 9 and 10, preferably made of stainless steel, is bent near the upper end portion 9 to form a first bend 1 which is referred to as a lower bend. The first bend 1 is hooked around a first pin 3 on a jig 6, the left portion of the wire 8 is hung inside a second pin 4, and the right portion of the wire 8 is hung on a third pin 5, as shown

in Figure 1B.

The distance between the first and second pins 3 and 4 is longer than that between the first and third pins 3 and 5. The second and third pins 4 and 5 are different from the first pin 3, in that the second and third pins 4 and 5 are bent horizontally and have an inner space in which to insert the wire. The wire 8 is inserted into the space formed by the bent pin 4 and the wire 8 is bent around the second pin 4 to form a second bend 2 which is referred to as an upper bend. Then, the wire 8 is twisted to a predetermined angle so that the wire 8 can form a desired shape.

A first straight section 7 is defined as the portion of the wire 8 between the first and second bends 1 and 2, as shown in Figure 1C.

Subsequently, second bend 2 is hung on the third pin 5 and the portion of the wire to the left of the second bend 2 is bent about first pin 3 to form a third bend 11 and a second straight section 17, as shown in Figure 1D. The third bend 11 belongs to the category of lower bends.

Since the first straight section 7 is formed between the first and second pins 3 and 4 and the second straight section 17 is formed between the first and third pins 3 and 5, the first straight section 7 is longer than the second straight section 17. Further, the first straight section 7 is twisted from the second straight section 17 by a predetermined angle because of the second and third pins 4 and 5, the shapes of which are not important, but which help to form a twisted angle between the first and second straight sections 7 and 17.

If such a process is continued, as illustrated in Figure 1E, a wire of a zigzag configuration, which has a plurality of first and second straight sections 7 and 17, lower bends 1, 11, 21, 31, ..., and upper bends 2, 12, 22, 32, ..., is formed. However, both end portions 9 and 10 of the wire 8 are left unbent.

A number of bends is selected for a first turn of the zigzag structure of Figure 1E and the upper bends of such a turn are cross-linked with the corresponding lower bends of the next turn, as shown in Figure 2. Eventually, the wire 8 has a plurality of spiral bends, thereby forming a cylindrical elastic body, as shown in Figure 3.

Referring to Figure 2, if the number of bends for a turn is 18, the 18th bend 82, which is one of the upper bends 2, 12, 22, 32, 42, 52, 62, 72, 82, 92, 102, ..., is cross-linked (or hooked) with the first bend 1. The 20th bend 92, which is also one of the upper bends, is cross-linked or hooked with a corresponding bend from the prior turn, namely the third bend 11, which is one of the lower bends. The 22nd bend 102 is stuck into the 5th bend 21 from inside to outside, and the 24th bend 112 is stuck into the 7th bend 31. The next turn, or a third turn, is formed in the same way as the first and second turns. That is, each of the upper bends of the third turn is cross-linked with a corresponding lower bend of the second turn.

Such a process is continued until a desired height of the stent, or a desired number of turns, is obtained. Then, the upper bends (2nd, 4th, 6th, 8th, ..., and 18th bends) are arranged spirally, the lower bends (the 1st, 3rd, 5th, 7th ..., and 17th bends) are also arranged spirally, and the cylindrical body is obtained as shown in Figure 3.

It is desirable to make the stent about 10 cm long. Each of the straight sections is preferably about 0.9 cm and the first straight sections 7 are slightly longer than the second straight sections 17. However, the length and the diameter of the stent are determined in accordance with the characteristics of the wire and the lumen where the stent is to be applied.

Ends 9 and 10 of the wire 8 are disposed at a top position and at a bottom position of the stent, respectively. The upper end 9 of the wire 8 extends diagonally in the direction of the bottom of the stent in such a manner that it weaves in and out of every turn or every third turn of the stent from inner side to outer side and from outer side to inner side of each turn. Finally, the upper end 9 is fixed by being wound around a straight section of a certain turn. The lower end 10 extends in the direction of the first turn and is wound around a straight section of a certain turn in a similar manner as the upper end 9. This configuration of the end portions 9 and 10 restrains the deformation of the stent in every direction thereof. It is of no consequence which end is defined as an upper end or lower end.

In the stent according to this invention, bends are arranged spirally and bends are hooked with each other like a chain link fence or net, and both ends are formed in the way described above. Therefore, the bends of the stent do not project outside the whole structure even in the case where the stent is bent due to the linking of the turns to themselves, which means that the passageway where the stent is applied maintains its opening and allows the blood to flow well. The interlinking of adjacent bends from each of the various turns serves to regulate and limit expansion and contraction of the stent. Further, the interlinking distributes force evenly and the elasticity of the stent is more uniform than that of prior stents. Still further, deformation in the longitudinal direction is limited by the ends being anchored (bent around) and woven through the different turns of the stent.

Since the stent obtained by the above process may have a larger diameter than is practical, it may be necessary to put it into a sleeve of desirable diameter and to treat it with heat.

Further, the stent may have to be wrapped in a mesh 13, and upper and lower hems of the mesh folded towards the inside of the stent, and both hems respectively adhered or fixed to themselves through the stent's circumference or to the wire. The mesh is such that it is not exposed. It is preferable that the mesh 13 is made of nylon and the entire mesh has a coating 14 made of silicon rubber. The coating 14 is formed as a hose-type membrane which is fitted around the stent and adhered

to it. This structure is already disclosed in patent publication WO 92/06734 by Song, Ho-young and U.S. Patent No. 5,330,500.

The coating 14 can be formed directly around the wire 8, but to increase the adhesive force, the mesh 13 is preferably wrapped around the wire 8 inside of coating 14. The effect of the coating is already known in this field, namely to prevent the growth of any tissue or to prevent restenosis.

The stent of this configuration is implanted in a blood vessel or other body cavity by means of an introducer or by implantation, as will be described below.

The introducer comprises an inner tube D and a guide G. The inner tube D helps the whole introducer to pass through the body cavity smoothly. First, the introducer, with the inner tube D inserted in the guide G, and with a stent C located between the guide G and the inner tube D, is inserted into the body cavity to a targeted position. The inner tube D is pulled out from the guide G, and the stent C, in its compressed shape, is pushed towards the opening of the guide G, at the desired position, by a pusher H. Finally, the guide G is pulled out of the body cavity and the stent C alone remains in the body cavity. The stent C subsequently expands and presses against a wall of the body cavity in order to maintain an open passageway.

As described above, the stricture of a lumen due to the growth of the tissue can be prevented. In addition, the stent according to the present invention does not permit penetration of tissue of the lumen. Additionally, the stent has a greater elastic force than prior stents.

In contrast to the stent disclosed in EP 0177330 issued to Cook Inc., which stent is connected by a plurality of straight line members for use, the stent of the present invention does not change longitudinally even when the stent experiences compression or expansion. This means that the stent does not change its position when the stent is placed in a desired position within a body cavity. Thus, once the stent is positioned exactly, there will be no deleterious expansion, contraction or movement thereof.

#### Claims

1. A self-expandable, cylindrical stent for expanding a lumen comprising: a single length of wire (8) bent into a zigzag configuration by forming alternating peaks and valleys, the zigzag configuration being spirally wrapped about an axis into a plurality of turns, said axis forming a longitudinal axis of the stent, and characterised in that peaks (1) of one turn of the stent are interlocked with valleys (82) of an adjacent turn of the stent by directly cross-linking said peaks and valleys.
2. A stent according to Claim 1, wherein the wire has first and second end portions (9,10) each of which is bent towards and extends towards a central turn

of the stent and is woven in and out of turns of the stent.

3. A stent according to Claim 2, wherein distal ends of the first and second end portions are hooked around a straight portion of a turn.
4. A stent as claimed in Claim 1, wherein the length of wire (8) consists of a series of first and second straight sections joined by a plurality of bends consisting of lower and upper bends, wherein each of the first and second straight sections is defined between each of the upper and lower bends, the first straight section (7) being longer than the second straight section (17) and the upper bends (2,12,22...) of one turn being directly cross-linked with corresponding lower bends (1,11,21...) of an adjacent turn, and wherein the stent is resiliently compressible into a smaller diameter first shape in which all of the straight sections are arranged side by side and closely adjacent one another for insertion into a passageway with the bends having a stress therein, the stent being resiliently radially expandable by release of said stress into a second shape in which it defines a generally cylindrical configuration for pressing against a wall of the passageway.
5. A stent according to Claim 4, wherein the wire has top and bottom end portions (9,10) which extend in a generally diagonal direction towards the bottom and the top of the stent, respectively, and which are woven in and out of turns of the wire from top and bottom ends of the stent, respectively, towards a center of the stent.
6. A stent according to Claim 5, wherein distal ends of the top and bottom end portions (9,10) are fixed by being wound around a straight section of a turn.
7. A stent, according to any one of Claims 4 to 6, in combination with a tubular guide (G) containing the stent such that the stent is resiliently compressed into said smaller diameter first shape.
8. The stent according to any preceding claim, wherein the stent additionally comprises coating means for preventing a tumor from penetrating gaps created by the stent.
9. The stent according to Claim 8, wherein the coating means is a nylon mesh (13).
10. The stent according to Claim 9, wherein the mesh is additionally coated with silicon rubber (14).

**Patentansprüche**

1. Sich selbsttätig ausdehnender zylindrischer Stent zum Aufweiten eines Lumens, zu dem ein in einem Zickzack geführter und dabei abwechselnd Scheitel- und Senkenabschnitte bildender Draht aus einem Stück (8) gehört, wobei die Zickzack-Konstruktion in mehreren Windungen spiralförmig um eine Achse herumgeführt ist und diese Achse eine Längsachse des Stents bildet, und der dadurch gekennzeichnet ist, daß die Scheitelabschnitte (1) einer Windung des Stents direkt mit den Senkenabschnitten (82) einer benachbarten Windung des Stents ineinandergreifen, indem die Scheitel- und Senkenabschnitte unmittelbar miteinander quervernetzt werden. 5
2. Stent nach Anspruch 1, bei dem der Draht einen ersten und einen zweiten Endabschnitt (9, 10) aufweist, die beide in Richtung auf eine mittlere Windung des Stents gebogen sind und sich in diese Richtung erstrecken und in Windungen des Stents durch Herein- und Herausführen eingeflochten sind. 10
3. Stent nach Anspruch 2, bei dem distale Enden des ersten und zweiten Endabschnitts durch Umwickeln eines geraden Abschnitts einer Windung verankert sind. 15
4. Stent nach Anspruch 1, bei dem der Draht in einem Stück (8) eine Anzahl von ersten und zweiten geraden Abschnitten bildet, die durch eine Anzahl von Biegungen, d.h. unteren und oberen Biegungen, verbunden werden, bei dem jeder erste und zweite gerade Abschnitt durch jeweils die obere und untere Biegung begrenzt werden, wobei der erste gerade Abschnitt (7) länger als der zweite gerade Abschnitt (17) ist und die oberen Biegungen (2, 12, 22...) einer Windung direkt mit den entsprechenden unteren Biegungen (1, 11, 21...) einer benachbarten Windung quervernetzt sind und bei dem der Stent elastisch zu einer ersten Form mit kleinerem Durchmesser zusammengedrückt werden kann, in der zum Einführen in eine Leitungsbahn alle geraden Abschnitte nebeneinander angeordnet sind und eng aneinanderliegen, wobei in den Biegungen eine Spannung wirkt und der Stent in radialer Richtung elastisch ausdehnbar ist, indem er durch Abbau dieser Spannung eine zweite Form annehmen kann, in der er eine im allgemeinen zylindrische Gestalt zum Fressen gegen die Wand der Leitungsbahn ergibt. 20 25 30 35 40 45 50
5. Stent nach Anspruch 4, bei dem der Draht einen oberen und einen unteren Endabschnitt (9, 10) aufweist, die sich im allgemeinen diagonal in Richtung unteres Ende bzw. oberes Ende des Stents erstrecken und die von den oberen bzw. unteren Enden des Stents aus in Richtung Mitte des Stents durch Herein- und Herausführen in Windungen des Drahts eingeflochten sind. 55

ken und die von den oberen bzw. unteren Enden des Stents aus in Richtung Mitte des Stents durch Herein- und Herausführen in Windungen des Drahts eingeflochten sind.

6. Stent nach Anspruch 5, bei dem distale Enden des oberen und unteren Endabschnitts (9, 10) durch Umwickeln eines geraden Abschnitts einer Windung verankert sind.
7. Stent nach einem der Ansprüche 4 bis 6, kombiniert mit einem Führungsschlauch (G), der den Stent so aufnimmt, daß er elastisch in die erste Form mit kleinerem Durchmesser zusammengedrückt wird.
8. Stent nach einem der vorstehenden Ansprüche, zu dem zusätzlich eine Hülle gehört, durch die verhindert wird, daß ein Tumor in die vom Stent gebildeten Lücken eindringen kann.
9. Stent nach Anspruch 8, bei dem die Hülle von einem Nylongeflecht (13) gebildet wird.
10. Stent nach Anspruch 9, bei dem das Geflecht zusätzlich mit Silikonkautschuk (14) ummantelt ist.

**Revendications**

1. Organe cylindrique d'écartement qui peut se dilater automatiquement et qui est destiné à écarter une lumière, comprenant un tronçon unique de fil métallique (8) courbé dans une configuration en zigzag par formation de crêtes et de creux qui alternent, la configuration en zigzag étant enroulée en spirale autour d'un axe sous forme de plusieurs spires, l'axe formant un axe longitudinal de l'organe d'écartement, caractérisé en ce que les crêtes (1) d'une spire de l'organe d'écartement sont emboîtées dans les creux (82) d'une spire adjacente de l'organe d'écartement par accrochage direct des crêtes et des creux. 30 35 40 45 50
2. Organe d'écartement selon la revendication 1, dans lequel le fil métallique a une première et une seconde partie d'extrémité (9, 10) courbées chacune vers une spire centrale de l'organe d'écartement, s'étendant vers cette spire et tissées vers l'intérieur et l'extérieur des spires de l'organe d'écartement.
3. Organe d'écartement selon la revendication 2, dans lequel les extrémités distales des première et seconde parties d'extrémité sont accrochées autour d'une partie rectiligne d'une spire.
4. Organe d'écartement selon la revendication 1, dans lequel le tronçon de fil (8) est constitué d'une

9

EP 0 645 125 B1

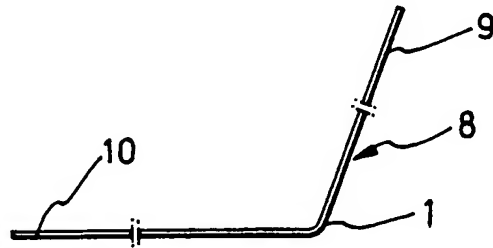
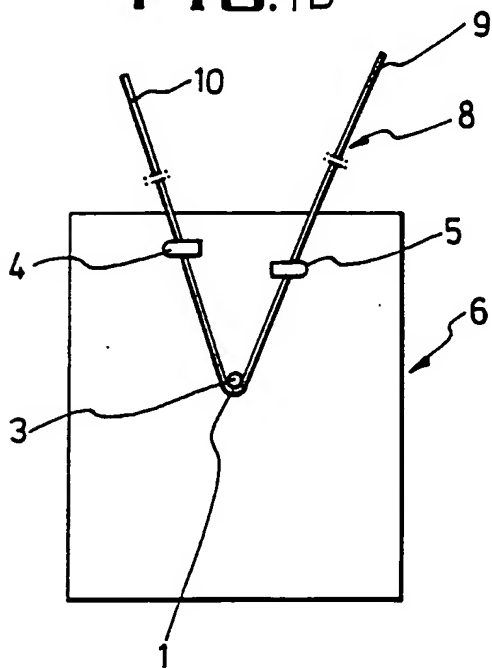
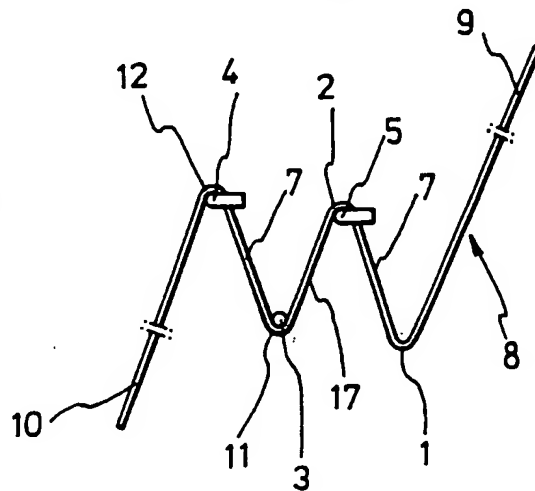
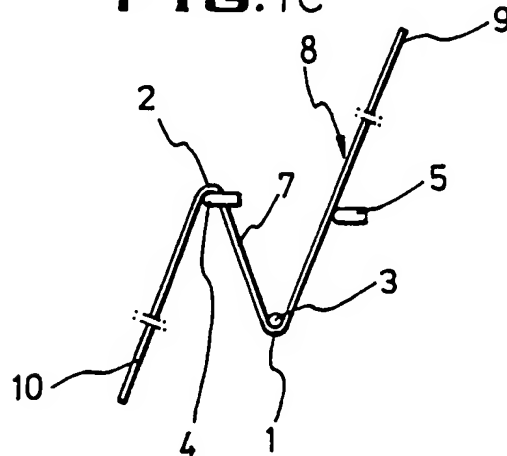
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série de premiers et seconds tronçons rectilignes raccordés par plusieurs coudes constitués de coudes inférieurs et de coudes supérieurs, dans lequel chacun des premiers et seconds tronçons rectilignes est délimité entre un coude supérieur et un coude inférieur, le premier tronçon rectiligne (7) étant plus long que le second tronçon rectiligne (17), et les coudes supérieurs (2, 12, 22,...) d'une spire étant directement raccordés aux coudes inférieurs correspondants (1, 11, 21,...) d'une spire adjacente, et dans lequel l'organe d'écartement est élastiquement compressible à une première forme de plus petit diamètre dans laquelle tous les tronçons rectilignes sont placés côte à côte et très près les uns des autres et peuvent être introduits dans un passage, les coudes ayant une contrainte, l'organe d'écartement pouvant se dilater élastiquement en direction radiale par suppression de la contrainte en prenant une seconde configuration dans laquelle il délimite une configuration cylindrique de façon générale destinée à exercer une pression contre une paroi du passage.

10. Organe d'écartement selon la revendication 9, dans lequel la grille est en outre revêtue d'un caoutchouc en silicone (14).

5. Organe d'écartement selon la revendication 4, dans lequel le fil métallique a des parties (9, 10) d'extrémité supérieure et inférieure qui s'étendent en direction diagonale de façon générale vers la partie inférieure et la partie supérieure de l'organe d'écartement respectivement et qui sont tissées dans les spires du fil, vers l'intérieur et vers l'extérieur, depuis les extrémités supérieure et inférieure de l'organe d'écartement respectivement vers le centre de l'organe d'écartement.
6. Organe d'écartement selon la revendication 5, dans lequel les extrémités distales des parties d'extrémité supérieure et inférieure (9, 10) sont fixées par enroulement autour d'un tronçon rectiligne d'une spire.
7. Organe d'écartement selon l'une quelconque des revendications 4 à 6, combiné à un guide tubulaire (G) contenant l'organe d'écartement de manière que l'organe d'écartement soit comprimé élastiquement à la première configuration de diamètre relativement petit.
8. Organe d'écartement selon l'une quelconque des revendications précédentes, dans lequel l'organe d'écartement comporte en outre un dispositif de revêtement destiné à empêcher une pénétration d'une tumeur dans les espaces formés par l'organe d'écartement.
9. Organe d'écartement selon la revendication 8, dans lequel le dispositif de revêtement est une grille (13) en nylon.

EP 0 645 125 B1

**FIG.1A****FIG.1B****FIG.1D****FIG.1C**

EP 0 645 125 B1

FIG.1E

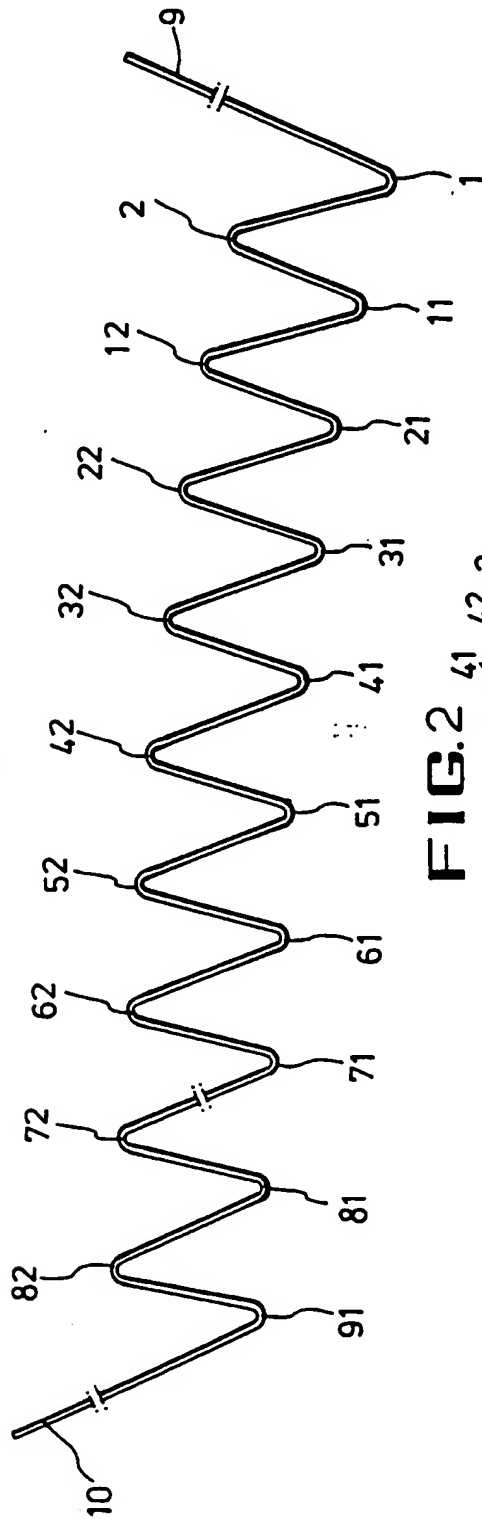
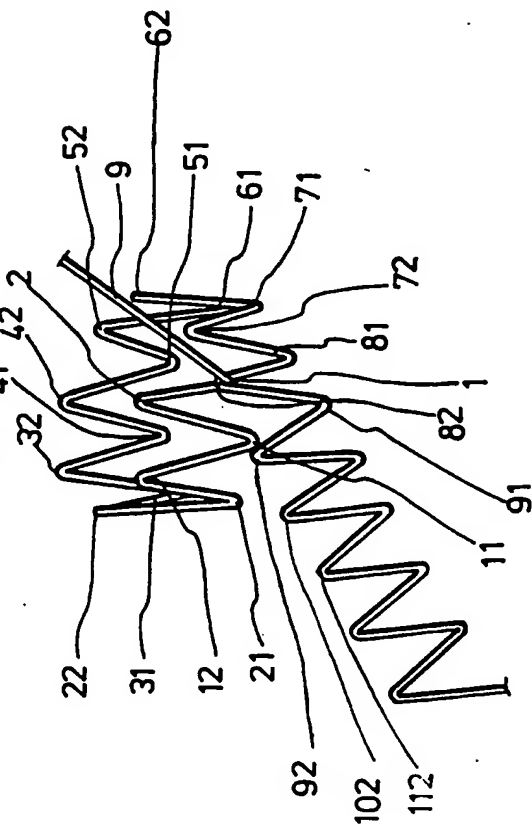
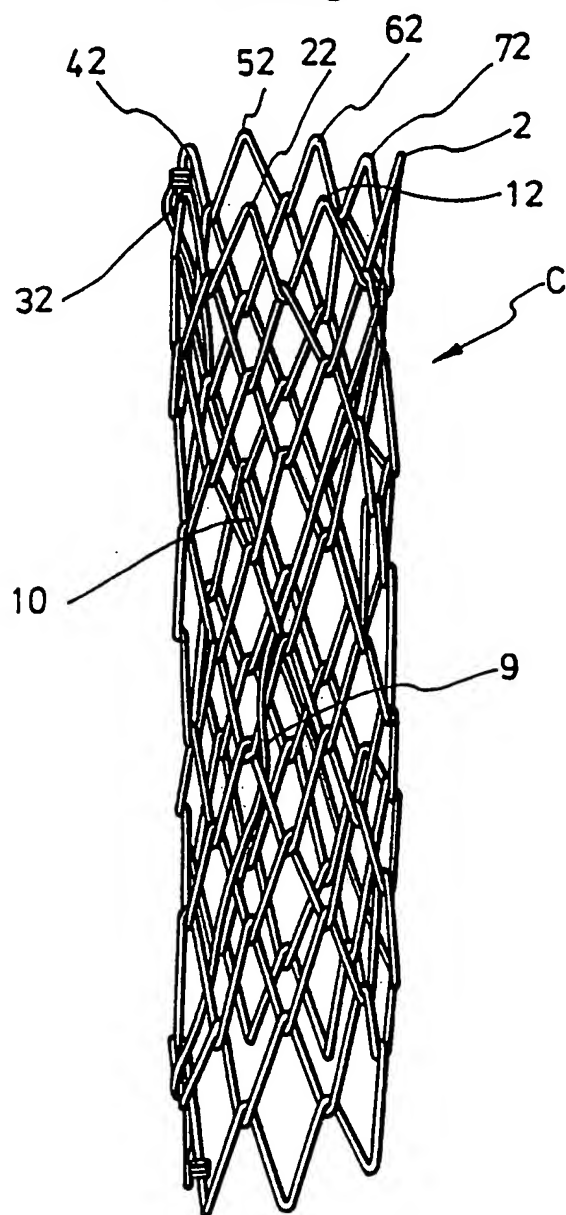


FIG.2



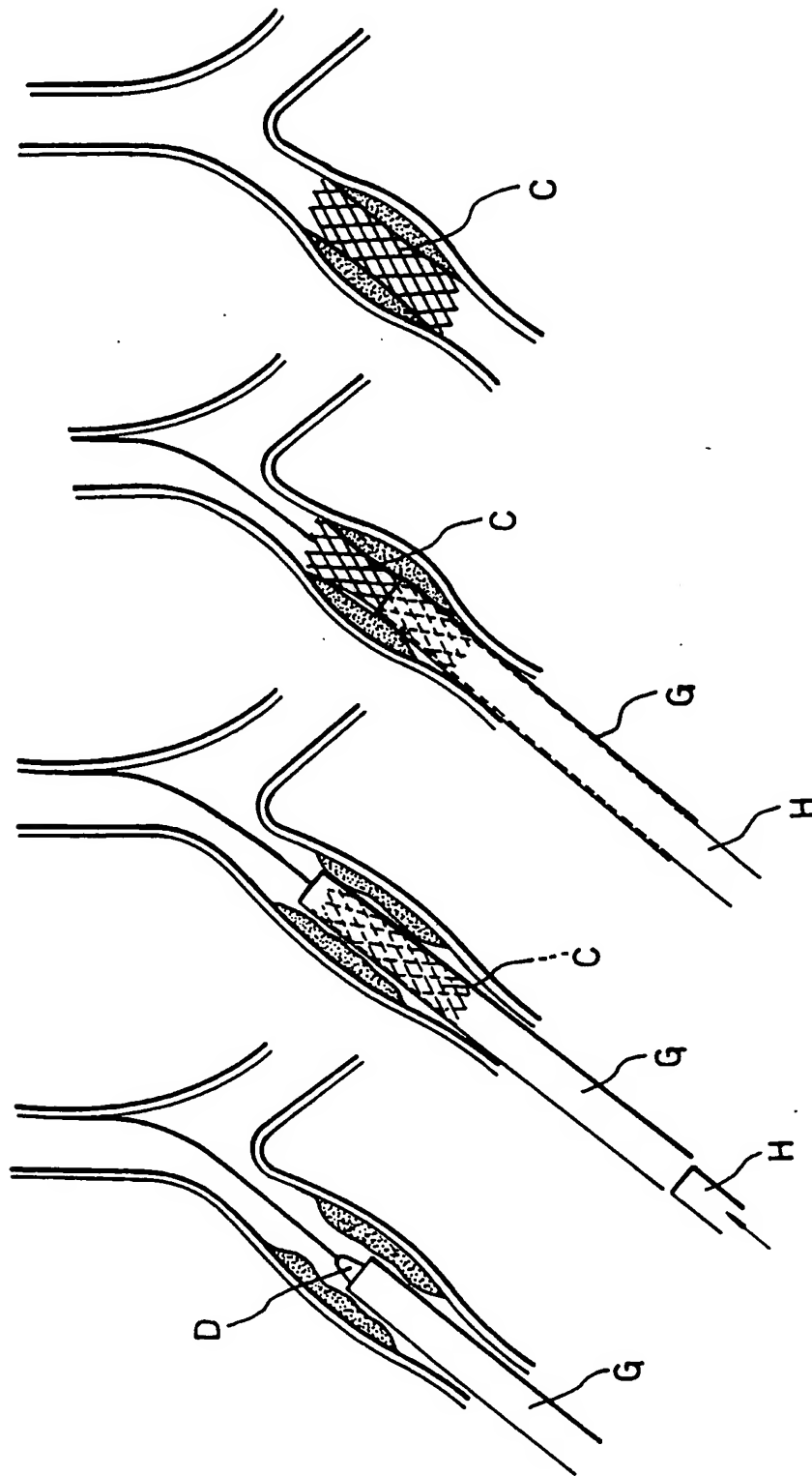


EP 0 645 125 B1

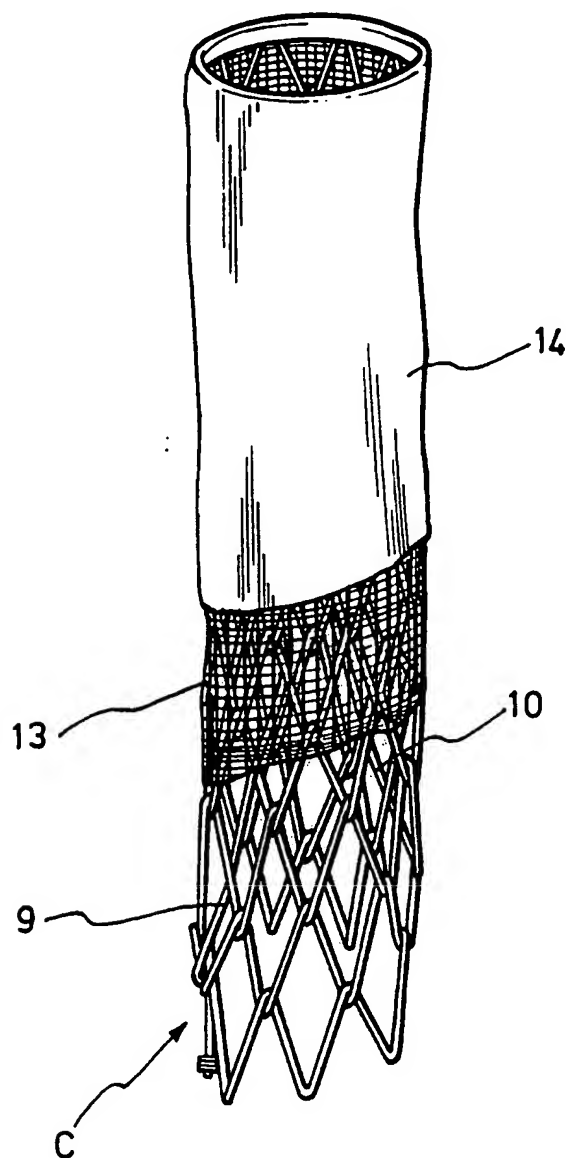
**FIG.3**

EP 0 645 125 B1

FIG.4A FIG.4B FIG.4C FIG.4D



EP 0 645 125 B1

**FIG. 5**

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